

## FACSIMILE COVER SHEET

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June 2, 2003

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**GROUP 1600**

**GROUP: 1631**

**FAX NUMBER: 1-703-872-9306**

**ATTORNEY DOCKET NO.: DEX-0289**

**SERIAL NO.: 09/989,919**

**FILED: November 21, 2001**

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(including this sheet)

**OFFICIAL**

**MESSAGE:** Attached is a Response to the Restriction Requirement dated May 2, 2003.

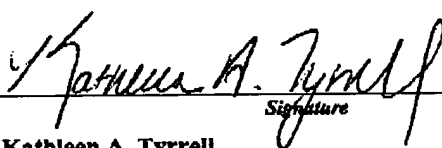
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<b>AMENDMENT TRANSMITTAL LETTER (Large Entity)</b>				Docket No. <b>DEX-0289</b>	
Applicant(s): <b>Macina et al.</b>					
Serial No. <b>09/989,919</b>	Filing Date <b>November 21, 2001</b>	Examiner <b>James Martinell</b>		Group Art Unit <b>1631</b>	
Invention: <b>COMPOSITIONS AND METHODS RELATING TO COLON SPECIFIC GENES AND PROTEINS</b>					
<b><u>TO THE COMMISSIONER FOR PATENTS:</u></b>					
Transmitted herewith is an amendment in the above-identified application. The fee has been calculated and is transmitted as shown below.					
<b>CLAIMS AS AMENDED</b>					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	19 -	20 =	0 x	\$18.00	\$0.00
INDEP. CLAIMS	2 -	3 =	0 x	\$84.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>					<b>\$0.00</b>
<input checked="" type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b> <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.					
 Kathleen A. Tyrrell Reg. No. 38,350 Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053 Tel: 856-810-1515 Fax: 856-810-1454			Dated: <b>June 2, 2003</b>		
<div style="border: 1px solid black; padding: 5px;">         I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.   <div style="text-align: center;">Signature of Person Mailing Correspondence</div>   <div style="text-align: center;">Typed or Printed Name of Person Mailing Correspondence</div> </div>					
cc:					



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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0289  
Inventors: Macina et al.  
Serial No.: 09/989,919  
Filing Date: November 21, 2001  
Examiner: Martinell, James  
Group Art Unit: 1631  
Title: Compositions and Methods Relating to  
Colon Specific Genes and Proteins

## Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile  
transmitted to the Patent and Trademark Office on  
the date shown below.

On June 2, 2003

  
Kathleen A. Tyrrell, Registration No. 38,350

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed May 2,  
2003 setting a one (1) month statutory period for response.  
Please enter the following remarks into the record.

**REMARKS**

Claims 1-17 are pending in the instant application. Claims  
1-17 have been subjected to a Restriction Requirement as follows:  
Group I, claims 1-9, 14/1 and 15/1, drawn to nucleic acids,

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nucleic acid molecular hybridization assays, vectors, host cells, kits and methods for producing polypeptides, classified in class 536, subclass 23.5 and class 435, subclasses 252.3, 325, 320.1; and 69.1;

Group II, claim 10, drawn to polypeptides, classified in class 530, subclass 350;

Group III, claims 12, 13, 14/6 and 15/6, drawn to antibodies, antibody assays, and kits, classified in class 530, subclass 387.1 and class 435, subclass 7.1;

Group IV, claim 16, drawn to a method for treatment using antibodies, classified in class 514, subclass 2;

Group V, claim 17, drawn to polypeptide vaccines, classified in class 514, subclass 12; and

Group VI, claim 17, drawn to polynucleotide vaccines, classified in class 514, subclass 44.

The Examiner suggests that the inventions of Groups I-VI are distinct.

Further, the Examiner suggests that claims 1-9, 14/1, 15.1 and 17 contain more than one individual, independent and distinct nucleotide sequence and that claims 10-13, 14/6, 15/6, 16 and 17 contain more than one unrelated, independent and distinct polypeptide sequence. Accordingly Applicants are required to

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select one individual sequence for examination.

Applicants respectfully traverse this Restriction Requirement and sequence election requirement.

With respect to the restriction of Groups I-VI, it is respectfully pointed out that there are two criteria which must be met for a restriction requirement to be proper. See MPEP § 803. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected sequence would also reveal any references teaching uses for this sequence. Accordingly, Applicants respectfully disagree with the Examiner that searching of all the claims, at least when limited to an elected sequence, is not overlapping and that undue burden is placed on the Examiner if the Restriction is not made. Thus, Applicants believe that this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper.

Further, with respect to election of a single sequence, Applicants respectfully disagree with the Examiner's suggestion that the sequences are unrelated. All sequences are related in the instant application by their identification as colon specific proteins and colon specific nucleic acids. Thus, reconsideration

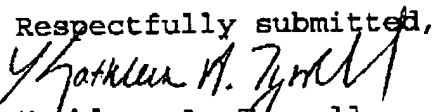
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is respectfully requested for inclusion of at least 10 sequences as this constitutes a reasonable number for examination purposes in accordance with MPEP §803.04.

Reconsideration and withdrawal of this Restriction Requirement and sequence election requirement is therefore respectfully requested.

However, in an earnest effort to be completely responsive to this Restriction Requirement, Applicants elect to prosecute Group I, SEQ ID NO:15, with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,  
  
Kathleen A. Tyrrell  
Reg. No. 38,350

Date: June 2, 2003

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